

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WISCONSIN

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PROMEGA CORPORATION,

Plaintiff,

MAX-PLANCK-GESELLSCHAFT ZUR  
FORDERUNG DER WISSENSCHAFTEN  
E.V.,

Case No.: 10-CV-281

Involuntary Plaintiff,

v.

LIFE TECHNOLOGIES CORPORATION,  
INVITROGEN IP HOLDINGS, INC., and  
APPLIED BIOSYSTEMS, INC.,

Defendants.

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**PROMEGA CORPORATION'S CLAIMS CONSTRUCTION REPLY BRIEF**

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**I. INTRODUCTION**

Defendants' Memorandum in Support of Motion Requesting Claim Construction ("Defendants' Mem.") makes clear that Defendants are not asking the Court to interpret the claims as granted by the Patent Office but to rewrite those claims. This request is based on the inapplicable and erroneous premise that the asserted claims, as actually stated in the Promega Patents, are invalid. Defendants ask the Court to rewrite the asserted claims to change them from being open-ended to being closed-ended (from "comprising" to "consisting of"), in terms of both the loci and the primers required by the actual claims, so that these claims will not, in Defendants' view, abridge the written description requirement of 35 U.S.C. §112 ("§ 112"). (Defendants' Mem., pp. 15-17).

The issue of whether or not the asserted claims, as actually stated in the Promega Patents, are invalid under the written description requirement of §112 is premature and presents a question on which Defendants bear the burden of proof. *Ariad Pharmaceuticals v. Eli Lilly*, 598 F.3d 1336, 1354 (Fed. Cir. 2010). If and when Defendants properly raise this question, Promega will establish that the asserted claims, as actually stated in the Promega Patents, are not invalid under the written description requirement of §112. That issue, however, is not presently before the Court. The only issue now before the Court is one of claim interpretation.<sup>1</sup>

Claim interpretation involves resort to the specification – but not for the purpose of importing limitations into the claims:

It is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim. *See, e.g., Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed. Cir. 1985). But this is not to be confused with adding an extraneous limitation appearing in the specification, which is improper. By “extraneous,” we mean a limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.

*E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988). In *du Pont*, the lower court determined that the claimed composition had properties that appeared to be different from the prior art. Then, without any particular term in need of interpretation, the lower court nonetheless imported these properties into the claim. Given that those limitations were not needed to interpret what the patentee meant by any particular term in the claim, the Federal Circuit reversed.

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<sup>1</sup> It is improper for a court to interpret or rewrite claims based upon a defendant’s premature allegation that, unless the claims are interpreted as requested by the defendant, the claims will be invalid. *See Sandisk Corp. v. Kingston Tech. Co., Inc.*, No. 10-cv-243-bbc, 2011 U.S. Dist. LEXIS 27696 at 37 (W.D. Wis. Mar. 15, 2011) (“[T]he possibility of a ruling of invalidity does not give the court the power to redraft the patent . . .”) Only after the claims have first been properly interpreted can an assessment of infringement and validity of the claims be made.

So too here. As to “loci” and “primer” and “primers for each locus,” the Defendants do not say that the meaning of these terms is unclear; rather, Defendants seek to import limitations from the specification, *e.g.*, limiting the claims to only the primers and loci set forth in the specification. This is improper.

## II. CLAIM CONSTRUCTION

### A. Claim term “a set . . . loci”

Defendants go to great lengths quoting the prosecution histories, specifications and expert opinions to convince the Court that the technology at issue at the time of the claimed inventions was uncertain and involved considerable experimentation with unpredictable results. (Defendants’ Mem., pp. 10-15). Promega does not dispute that the technology at issue at the time of the claimed invention was, in Defendants’ words, “unpredictable and failure-ridden.” (*Id.* at 12). While these facts do support Promega’s position that the claimed inventions are not obvious, they do not logically or legally, support Defendants’ argument that the claim term “a set . . . loci” must be “construed” to change the claim as allowed from its open-ended character, allowing but not requiring additional loci, to a closed-ended character precluding additional loci.

Defendants’ primary argument for the change they propose is that unless Defendants’ construction is adopted the claims will be invalid under the written description requirement of §112.<sup>2</sup> This invalidity argument does not relate to how the claims should be construed and should be ignored. *See Sandisk Corp. v. Kingston Tech. Co., Inc.*, No. 10-cv-243-bbc, 2011 U.S. Dist. LEXIS 27696 at 37 (W.D. Wis. Mar. 15,

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<sup>2</sup> Defendants rely on a number of cases which are not claim construction cases; rather, they involve inquiries into written description and/or enablement. These cases include: *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005) (Defendants’ Mem., pp. 12-13, 15-16, 17, 25, 27); *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 (Fed. Cir. 2000) (Defendants’ Mem., pp. 15, 17, 25); *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004) (Defendants’ Mem., p. 16); and *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336 (Fed. Cir. 2005) (Defendants’ Mem., p. 17).

2011) (“[T]he possibility of a ruling of invalidity does not give the court the power to redraft the patent . . .”). A determination of validity is to be made only after the claims have been properly construed.

The *Renishaw* case, cited by Defendants, does not support Defendants’ argument. The section of *Renishaw* quoted by Defendants explains two canons of claim construction: “(a) one may not read a limitation into a claim from the written description, but (b) one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part.” *Renishaw PLC v. Marpos Societa’ Per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998); (Defendants’ Mem., p. 12). The central point made by the Court was that the language of the claim itself controls and cannot be changed, added to, nor supplemented by the written description, file history or extrinsic evidence but can only be interpreted, if interpretation is needed.

First, it is manifest that a claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description. This is so because the claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim . . . .

*Id.* (citations omitted).

The Supreme Court has clearly stated the rationale for this requirement: [W]e know of no principle of law which would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty or infringement. The difficulty is that if we once begin to include elements not mentioned in the claim in order to limit such claim . . . , we should never know where to stop.

*Id.* at 1248-49 (citation and quotation omitted).

Even the very passage from *Renishaw* cited by Defendants supports Plaintiff’s—not Defendants’—proposed claim interpretation.

Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389, 116 S.Ct. 1384, 134 L.Ed.2d 577, 38 USPQ2d 1461, 1470 (1996). The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

*Id.* at 1250 (emphasis added).<sup>3</sup>

When one looks at the actual claim language stated in the patents, rather than the redacted claim term proposed by Defendants that omits critical clarifying language (*e.g.*, “a set of . . . loci” versus “a set of at least three short tandem repeat loci of the DNA sample to be analyzed”), it is clear that *Renishaw’s* teachings are directly contrary to the Defendants’ suggestive error. All of the claim language must be considered – not just some of the claim language.<sup>4</sup> Three examples illustrate Defendants’ error.

1. The actual language of the claim term identified by Defendants in Claim 1 of the ‘598 Patent element b) is:

selecting a set of at least three short tandem repeat loci of the DNA sample to be analyzed which can be co-amplified, wherein the at least three short tandem repeat loci in the set comprises at least three loci selected from the group consisting of:

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<sup>3</sup> The *Praxair* and *C.R. Bard* cases also cited by Defendants do not support limiting the claims in the manner Defendants suggest. *Praxair, Inc. v. ATMI, INC.*, 543 F.3d 1306 (Fed. Cir. 2008); *C.R. Bard, Inc. v. United States Surgical Corp.*, 388 F.3d 858 (Fed. Cir. 2004). The passage of *Praxair* relied on by Defendants simply states that claims should be read in light of the specification’s consistent emphasis on this fundamental feature of this invention. *Praxair, Inc.*, 543 F.3d at 1324. *Praxair* provides no suggestion that any claims should be construed to be close-ended. Similarly, Defendants quotation of *C.R. Bard* is unhelpful to Defendants’ argument. *C.R. Bard* explains only that “[s]tatements that describe the invention as a whole, rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term.” *C.R. Bard, Inc.*, 388 F.3d at 864.

<sup>4</sup> Claim construction requires that all of the language of the claim be considered. *Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (“A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.”); *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 766, 770 (Fed.Cir.1996) (rejecting the district court’s claim construction because it rendered superfluous the claim requirement for openings adjacent to the end walls).

In order to arrive at Defendants' proposed construction, one must eliminate the actual words of the claim that are stricken through below and add the words in bold and italics:

selecting a set of ~~at least three~~ short tandem repeat loci of the DNA sample to be analyzed which can be co-amplified, wherein the ~~at least three~~ short tandem repeat loci in the set ~~comprises at least~~ ***consists of*** three loci selected from the group consisting of:

2. The actual language of the claim term identified by Defendants in Claim 1 of the '660 element b) is:

selecting a set of at least four short tandem repeat loci of the DNA sample to be analyzed which can be amplified together, wherein the at least four loci in the set are selected from the group of loci consisting of:

In order to arrive at Defendants' proposed construction, one must eliminate the actual words of the claim that are stricken through below and add the words in bold and italics:

selecting a set of ~~at least~~ four short tandem repeat loci of the DNA sample to be analyzed which can be amplified together, wherein the ~~at least four loci in the set are~~ ***consists of four loci*** selected from the group of loci consisting of:

3. The actual language of the claim term identified by Defendants in Claim 1 of the '235 element b) is:

selecting a set of loci of the DNA sample, comprising

In order to arrive at Defendants' proposed construction, one must eliminate the actual words of the claim that are stricken through below and add the words in bold and italics:

selecting a set of loci of the DNA sample, ~~comprising~~ ***consisting of***

The construction that stays true to the actual claim language and most naturally aligns with the patent's description of the invention in this case is the language of the claims as drafted by the patentee and allowed by the USPTO. In accordance with *Renishaw*,<sup>5</sup> Plaintiff's construction is the correct construction, not Defendants' proposal to rewrite the claims to avoid misguided invalidity arguments.

Similarly, Defendants' reliance on *Dippin' Dots, Inc. v. Mosey* is misplaced. 476 F.3d 1337 (Fed. Cir. 2007); (Defendants' Mem., pp. 18-20). In *Dippin' Dots*, one of the steps, or elements/limitation, of the method claim specifically required "freezing said dripping alimentary composition into *beads*." *Dippin' Dots, Inc.*, 476 F.3d at 1340. The patentee in *Dippin' Dots* argued that the term "comprising," which appeared in the preamble, not in the limitations of the claim, broadened the scope of the step requiring freezing "into beads." *Id.* at 1343. However, the patentee had defined the term "beads" in a very narrow manner in the specification. *Id.* That is to say, the patentee had adopted a narrow technical definition for the term "beads." The Federal Circuit held that the term "comprising" in the preamble did not broaden the scope of the term "beads" beyond how it was defined in the specification of the patent:

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<sup>5</sup> *Renishaw* teaches that claim language is controlling. *Renishaw PLC*, 158 F.3d at 1248. Defendants also cite *Renishaw* regarding what "the inventors actually invented." (Defendants' Mem., p. 12). However, Defendants have not provided the complete quote. The sentence from *Renishaw* quoted by Defendants purporting to support their proposed claim construction method actually states in full: "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented **and intended to envelop with the claim**." *Renishaw PLC*, 158 F.3d at 1250 (emphasis added). When read in context, it is clear that Defendants' implication to limit claims to what the inventor actually invented, is unwarranted. One must also look to what the inventors "intended to envelop with the claim." After the claims are properly interpreted in accordance with these canons, the Court then looks to the issues of infringement and validity as defined in Title 35 of the U.S.C., not to the notion of "what the inventor actually invented." Nowhere in this quotation, or anywhere else in *Renishaw*, is there even a suggestion that the courts should limit (in this case rewrite) claims to conform to this notion of "what the inventors actually invented."

The presumption raised by the term “comprising” [*i.e.*, that the list of elements is non-exclusive] does not reach into each of the six steps to render every word and phrase therein open-ended – especially where, as here, the patentee has narrowly defined the claim term it now seeks to have broadened.

*Id.*

The issue presented by Defendants’ proposed claim construction is not the application of the term “comprising” that appears at the end of the preamble in the Promega Patents, as was the issue in *Dippin’ Dots*. Promega does not seek to modify a definition for a technical term in the specification with language in the preamble. Promega’s patent claims have language, separate and apart from the preamble, in the body of each of the asserted claims directed to either a set of at least a defined number of loci and/or as comprising specifically defined loci rendering all of these claims open-ended in terms of the number of loci present in the multiplex amplification reaction.

It should also be noted that in Promega Patents ‘598 and ‘660, the preamble of the claims in addition to containing the term “comprising” at the end, also define the claimed invention as a method of “determining the alleles present in at least three short tandem repeat loci” and “determining the alleles present in at least four short tandem repeat loci” respectively. This claim language supports Promega’s proposed claim interpretation by clearly and unequivocally stating what the inventors “intended to envelop with the claim” and establishes that Promega’s proposed construction is the correct construction because it “stays true to the claim language and most naturally aligns with the patent’s description of the invention.” *Renishaw PLC*, 158 F.3d at 1250.

Moreover, as noted in Promega’s Opening Claims Construction Brief, Defendants’ proposed claim construction for “a set of . . . loci” directly conflicts with this



Court's prior claim construction for Promega Patents '598 and '660. *Promega Corp. v. Applera Corp.*, 3:01-CV-244-bbc (W.D. Wis. June 10, 2002) (Order). Defendants' Opening Brief failed to address this earlier ruling, although acknowledging its existence. (Defendants' Mem., p. 2, n. 3). As explained in Promega's Opening Claims Construction Brief, the fact is that if the Court were to adopt Defendants' proposed claim construction, it would create the anomaly that dependent claims of the Promega Patents could be infringed without a corresponding infringement of the independent claims upon which the dependent claims are based. The existence of this anomaly precludes adoption of the Defendants' proposed claim construction of the term "a set of . . . loci."

Finally, Defendants look to the prosecution history, but nothing in the prosecution history further limits the claims. The Defendants argue, for example, that the specific loci listed in the claims were not previously multiplexed. (*See* Defendants' Mem., p. 13) ("Multiplex analysis of the sets of loci disclosed herein has not been previously described in the prior art."); (*see also* Defendants' Mem., p. 14) ("The combined references do not disclose or even suggest the presently claimed combinations of loci . . ."). The Defendants fail to read these statements in context.

In the case of the '598 Patent prosecution, such statements were made at the point where certain claims were limited to "at least three loci" (from "at least two loci") and where the particular combinations of loci were specified in the claim. (*See* Amendment mailed May 30, 2000 where Claim 21, which later became Claim 1 of the issued '598 Patent, was amended in this manner; and where Claim 34, which later became Claim 10 of the issued '598 Patent, was amended in this manner (Sun Decl., Exh. 3-1, pages 141-144 (pages 1-4 in original))). There was no disclaimer of subject matter beyond requiring

at least three loci instead of at least two. The statements did not further limit the claims. The claims remain open-ended and the statements would not preclude use of the described sets of STR loci in conjunction with other STR loci.

Defendants also point to the examiner's statement for the reasons for allowance of the '598 Claims. (*See* Defendants' Mem., p. 15). Again, there is no further limitation to the '598 Claims that can be inferred from the examiner's statement. The examiner simply indicated that the recited combinations of STR loci in the claims were not contemplated for multiplexing in the prior art. This did not change the claim from open-ended or preclude use of the described sets of STR loci in conjunction with other STR loci.

It must be emphasized that the examiner permitted Claims 1 and 10 of the '598 Patent to issue with "comprising" in the preamble and "at least three" modifying "loci" in numerous places in the body of the claim. Had the examiner insisted on a more narrow claim, and had applicants agreed, more narrow language (*e.g.*, "consisting") would have been employed. However, such was not the case.

In the case of the '660 Patent prosecution, the "at least" language was in many of the claims at the time of filing (*e.g.*, original Claims 1-5). During the prosecution, a locus was dropped from Claim 1. (*See* Amendment mailed May 9, 1997 at Exhibit 2-2 of the Sun Declaration, p. 220). However, because of the language of the claim, it was argued that Claim 1 still encompassed the locus as a possible locus in a set:

Claim 1 has also been amended to delete one locus . . . from the Markush group of loci provided therein. However, applicants submit that the amendments to Claim 1 do not change the fact that the claimed method encompasses the co-amplification and evaluation of sets of . . . loci which include the deleted locus,

provided at least four of the loci in the set . . . are selected from the remaining group of loci listed in Claim 1.

(*Id.* at 8-9). This is consistent with the “comprising” and “at least” language in the claim.

**B. Claim term “gel”**

The term “gel” was not given a particular definition by the patent applicants; accordingly, it is given its ordinary and customary meaning. As the Court noted in

*Renishaw*:

**For example, if an apparatus claim recites a general structure (e.g., a noun) without limiting that structure to a specific subset of structures (e.g., with an adjective), we will generally construe the claim to cover all known types of that structure that are supported by the patent disclosure. See, e.g., *Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 865-66, 45 USPQ2d 1225, 1229 (Fed.Cir.1997) (claim term “reciprocating” is given its ordinary meaning and not limited to mere linear reciprocation); *Sjolund v. Musland*, 847 F.2d 1573, 1581-82, 6 USPQ2d 2020, 2027 (Fed.Cir.1988) (refusing to limit claim term “baffle” to only rigid baffles and term “panel” to only panels of lattice construction).**

*Renishaw PLC*, 158 F.3d at 1250 (emphasis added). Applying these canons of claim construction here results in the straightforward conclusion that the general term “gel,” as it appears in the asserted claims without a limiting modifier, cannot be changed to include the Defendants’ proposed limiting modifier. Nor should that modifier be added to the claims when the term “gel” already contains a modifier, as it does, for example, in claim 5 of the ‘598 Patent which requires a denaturing polyacrylamide gel. In this last instance, it is clear that the term “gel” is used in its broad sense such that, if standing alone, it would encompass all types of gels that are supported by the patent’s disclosures not just denaturing polyacrylamide gels.

The disclosures of the Promega Patents repeatedly support various types of “gels.” For example, the Promega Patents acknowledge that there are a number of types of electrophoresis using a variety of gels:

These amplified products are generally separated by *one of several methods of electrophoresis* known to those skilled in the art.

(‘598 Patent at Col. 2, lines 7-10 (emphasis added)). In the background section of the Promega Patents, there is mention of electrophoresis using agarose gels:

According to Fortina et al., multiplex PCR has also been used for simultaneous amplification of multiple target sequences, permitting mutant allele scanning using two lanes of an *agarose gel*.

(‘598 Patent at Col. 2, lines 28-31 (emphasis added)). The Promega Patents specifically indicate that capillary gel electrophoresis (“CE”) can be used:

Capillary electrophoresis . . . to analyze and compare the relative lengths of alleles of each locus amplified in a multiplex reaction.

(‘235 Patent at Col. 4, lines 27-29). Indeed, asserted Claim 6 of the ‘235 Patent encompasses both electrophoresis techniques: “wherein the amplified alleles are separated prior to evaluating in step (d), using a separation means selected from the group consisting of polyacrylamide gel electrophoresis and capillary gel electrophoresis.” While the term “gel” is used in each case, the nature of the gel need not be (and typically is not) the same for each technique. (*See* Dimond Declaration, ¶ 19 (Dkt. #155)).

There is no reason why the term “gel” should not be given a broad interpretation and certainly no reason to adopt Defendants’ limiting modifier that finds no support whatsoever in the intrinsic evidence. Defendants offer no valid basis in the canons of claim construction for requiring the term “gel” to be modified to include only gels that consist of “three dimensional cross-linked networks.”

Setting aside the claim language and the specification, the Defendants turn to a single statement in a declaration by James Schumm, one of the inventors, submitted during prosecution of the '660 Patent, in an effort to support their proposed definition for gel as a three-dimensional cross-linked network. (Defendants' Mem., p. 21). In context, however, that statement says nothing about limiting the meaning of gel, let alone to limit the term "gel" to only cross-linked material.

The Schumm declaration was attached to a claim amendment adding two new claims to the application neither of which says anything about gels. As shown by a review of a more complete version of the Schumm paragraph cited by Defendants, the discussion concerning gels was offered to support an argument of non-obviousness and was not directed to limiting the inventions to cross-linked material:

New proposed Claims 47 and 48 are directed to preferred forms of the method and kit of the present invention, respectively. In this preferred form . . . at least four of the labeled primers are labeled with the same fluorescent label.

\* \* \*

. . . it would not have been obvious to a skilled artisan to develop any STR multiplex analysis method or kit which included at least four primers labeled with the same color fluorescent label, because numerous barriers to the development of any such system were known . . . First, a skilled artisan would have known that the principal tool used to separate amplified STR loci, polyacrylamide denaturing gel electrophoresis, is inherently limited in its capacity to resolve amplified DNA fragments, which differ as little from one another in length as DNA fragments produced by co-amplified multiple STR loci.

(Sun Decl., Exh. 2, p. 260).

The declaration cited by Defendants contains neither reference to "three dimensional cross-linked networks" nor any reference that seeks to limit "gels" in any fashion. The only reference to gels concerns the identification of polyacrylamide denaturing gels as a principal, clearly not the only, gel to be used in the invention. Dr.

Schumm did not offer a definition for “gel,” he merely discussed the problems with polyacrylamide denaturing gels, one of the tools generally used. The quoted language offered by Defendants does not support a limited definition for the term “gel,” let alone a limitation to only “three dimensional cross-linked networks.”

The only other basis offered by Defendants for their proposed limited definition of “gel” is extrinsic evidence. (See Defendants’ Mem., p.21). The Federal Circuit has made clear that intrinsic evidence is preferred and that extrinsic evidence should only be used as further guidance, *i.e.*, it is not controlling and ought not be used absent some relationship to the intrinsic evidence. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005); *id.* at 1318 (“[E]xtrinsic evidence by definition is not part of the patent and does not have the specification’s virtue of being created at the time of patent prosecution for the purpose of explaining the patent’s scope and meaning.”). Reliance on dictionary definitions divorced from the intrinsic evidence creates the risk of improper claim construction:

The main problem with elevating the dictionary to such prominence is that it focuses the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. Properly viewed, the “ordinary meaning” of a claim term is its meaning to the ordinary artisan after reading the entire patent. Yet heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification. The patent system is based on the proposition that claims cover only the invented subject matter.<sup>6</sup> As the Supreme Court has stated, “it seems to us that nothing can be more just and fair, both to the patentee and the public, than that the former should understand, and correctly describe, just what he has invented, and for what he claims a patent.” *Merrill v. Yeomans*, 94 U.S.

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<sup>6</sup> Defendants repeatedly quote this single sentence for different purposes. (*See* Defendants’ Mem., pp.12, 15, 22). However, it is clear that the “claims cover only the invented subject matter” language used by the *Phillips* Court is in the context of not allowing a specialized dictionary definition to override the plain meaning of the claims. The sentence cannot be read in context to mean that claims cannot be open-ended so as to encompass downstream improvements.

[568,] 573-74 [(1876)]. The use of a dictionary definition can conflict with that directive because the patent applicant did not create the dictionary to describe the invention. Thus, there may be a disconnect between the patentee's responsibility to describe and claim his invention, and the dictionary editors' objective of aggregating all possible definitions for particular words.

*Id.* at 1321 (footnote added). Here the defendant offers a self-serving definition of gel from one of many dictionaries without any explanation or reasonable basis of why the definition chosen has any relevance or relationship to the term "gel" as actually used in the patent claims.

Promega suggests that, if a dictionary definition is to be used, the definition based on the Random House Dictionary for a "gel" in the biochemistry context, which is the field that is the subject matter of the asserted patents, found at dictionary.com, be used:

a semirigid polymer, as agarose, starch, cellulose acetate, or polyacrylamide, cast into slabs or cylinders for the electrophoretic separation of proteins and nucleic acids.

This is a generally accepted definition found in many dictionaries of chemistry and biochemistry and is consistent with the intrinsic evidence discussed above. (*See* Dimond Declaration, ¶ 19 (Dkt. #155)). There is simply no basis for the Defendants' proposed definition.

**C. Claim term "primers for co-amplifying . . . loci"  
"primers for each locus"; and  
"primers flanking the loci."**

The Defendants' argument concerning primers is virtually identical to that presented for Defendants' proposed construction of "a set . . . of loci." (Defendants' Mem., p. 22). Defendants argue that identifying primers for the multiplexes identified in the asserted claims was a "difficult and arduous process" and that "[p]rimer sequences other than those listed in the Promega Patents for each locus are beyond [the] scope of the

alleged inventions.” (Defendants’ Mem., pp. 24 -25). Defendants then repeat the argument that because of that process, Promega’s claims are invalid for failure to meet §112’s written description requirement. Defendants conclude: “In this case, in order for the claims to be commensurate with the scope of the alleged invention, the “primer” claim terms must be construed as the “specific primer sequences listed in the patent for each locus.” (Defendants’ Mem., p. 27).<sup>7</sup>

As with “loci,” the issue of whether or not the asserted claims, as actually stated in the Promega Patents, are invalid under §112 is premature and presents a question on which Defendants bear the burden of proof. *Ariad Pharmaceuticals*, 598 F.3d at 1354. If and when Defendants properly raise this factual issue, Promega will establish that the asserted claims, as actually stated in the Promega Patents, are not invalid under §112. That issue, however, is not presently before the Court. The only issue now before the Court is one of claim interpretation.

As noted in Promega’s Opening Claims Construction Brief, many of the asserted claims do not even contain the term “primer.” Moreover, in the cases where the claims do contain this term, there is no basis for limiting the claims to only the primers set forth in the specification.

For example, Claim 10 of the ‘598 Patent contains the term “primer” but also uses “at least” language repeatedly throughout the body of the claim:

10. A kit for simultaneously analyzing short tandem repeat sequences in at least three loci, comprising:

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<sup>7</sup> In addition to these items Defendants also make an argument based on a restriction requirement during the prosecution of the ‘235 Patent. It is so strained that it warrants little notice. (Defendants’ Mem., pp. 28-29). Defendants confuse “invention” with “embodiments.” The quoted language on page 29 of the Defendants’ Opening Brief clearly indicates the claims are directed to “two different embodiments.” Moreover, even if (somehow) the response to the restriction requirement implicated primers in the method step, it certainly does support limiting the claims to specific primer sequences.



a single container containing oligonucleotide primers for each locus in a set of at least three short tandem repeat loci, wherein the at least three short tandem repeat loci in the set comprises at least three loci selected from the group consisting of:

(‘598 Patent Claims (emphasis added)). The meaning of “primers” in Claim 10 cannot be divorced from its context, and that context includes the “at least” language. The language makes it clear that the number of primers cannot be construed to be limited to just those three sets of primers for just three loci.

As noted earlier, the dependent claims which DO specify particular primer sequences, under the doctrine of claim differentiation, make it clear that the independent claims are not to be limited to these specific primer sequences. (Promega’s Opening Claims Construction Brief, p. 16); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (the doctrine is at its strongest “where the limitation sought to be ‘read into’ an independent claim already appears in a dependent claim”).

Finally, the specification itself makes it clear that other loci and primers are contemplated to be within the scope of the claims:

Successful combinations *in addition to those disclosed herein* can be generated by trial and error of locus combinations, by selection of primer pair sequences, and by adjustment of primer concentrations to identify an equilibrium in which all included loci may be amplified. Once the method and materials of this invention are disclosed, various methods of selecting loci, primer pairs, and amplification techniques for use in the method and kit of this invention are likely to be suggested to one skilled in the art. ***All such methods are intended to be within the scope of the appended claims.***

(*See, e.g.*, the '660 Patent at Col. 12, lines 46-56 (emphasis added)). For all of these reasons, there is no basis for limiting “primers” to only the specific primers in the specification.<sup>8</sup>

## CONCLUSION

The Defendants’ proposed constructions, in large measure, attempt to narrow the asserted claims based solely on the argument that the claims, as actually allowed, are invalid if Defendants proposals are not adopted. Setting aside that invalidity contentions are premature and, if made, would be hotly contested, such arguments, in the context of this claim construction, provide no legal basis for accepting Defendants proposals. Defendants’ request to import language into the claims having no relationship to the intrinsic evidence is contrary to the law of claim interpretation and must be rejected.

The actual an unambiguous language of the asserted claims controls. Defendants’ proposed constructions must be rejected, and those of the Plaintiff must be adopted.

Respectfully submitted this 6th day of May, 2011.

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<sup>8</sup> At sections D and E of Defendants’ Mem, Defendants argue that their proposed claim construction for the terms “multiplex amplification . . . using . . . primers” and “co-amplifying . . . loci” should be adopted “for the same reasons given above with respect to the claim terms “primers for co-amplifying . . . loci”; “primers for each locus”; and “primers flanking the loci” (Defendants’ Mem., pp. 27, 28). For the same reasons noted above in this brief, Defendants proposed claim constructions should be rejected.